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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,969

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/606,969	Applicant(s) CHEN ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,7-26,29-34,36,38,39,44-56,59,60 and 105-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,7-26,29-34,36,38,39,44-56,59,60 and 105-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 10/27/2008, has been received. Claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60, 105-124 are pending, and treated on the merits in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7-26, 29-34, 36, 38-39, 44-56, 59-60, 105-124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 2, 29, 59 and 105 now recite a composition that "retains its gel-like consistency after implantation". It is unclear what consistencies are "gel-like" as recited. How do "gel-like" consistencies differ from 'gel consistencies'?

The remaining claims are rejected for ultimately depending on one or more of the abovementioned claims without clarifying this issue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 9-26, 29-34, 36, 38-39, 46-56, 59, 105-116, 119-124 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,130,200 to Brodbeck.

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Brodbeck teaches a composition comprising a PIA polymer having a low molar weight (col. 14), a solvent that is preferably an ester of an aromatic alcohol (col. 13) and a beneficial agent (claim 1, examples). The solvent may be, *inter alia*, benzyl benzoate, ethyl benzoate, and mixtures. Col. 13. The polymer molecular weight may be 1,000 to 120,000 Da, or 8,000-13,000 Da. Col. 14, claim 15. A PLGA polymer polymer is a "lactic acid polymer" as it contains lactic acid monomers. The polymer may be present in 40% of the composition by weight. Example 1. Pore formers, solubility modulators, and osmotic agents may be added. Claims 5-7. The beneficial agents that may be used include those of instant claims 21 and 22. Example 2 (human growth hormone), Col. 19-20. The beneficial agent is present from 1-50% by weight, or from 5-30% by weight, or from 10-21% by weight. Col 21. The depot is a gel that, in some embodiments, comprises particles of the beneficial agent. Example 2 (particle of human growth hormone). The particle size in Example 2 is 2-100 microns. An emulsifying agent (stabilizing agent in instant claims) may be included. Claims 6, 11. The solvents may be mixed, and preferably 80% of the solvent is benzyl benzoate. Col. 13. Less than 25% of the drug is delivered within the first day (reading on about 20% or less of instant claim 124). Col. 14, last paragraph.

What is lacking is:

- 1) The polymer need not be the requisite molecular weights.
- 2) The requisite solvents are not required.
- 3) There is no specific disclosure of delivering beneficial agent for less than 7 days.

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It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the polymers in the requisite molecular weight, and to use the requisite solvents of instant claims. Both of these elements are suggested by the art, although not specifically required. With regard to delivery of beneficial agent for less than 7 days, it is noted that the claims are drawn to a product, not to a method of delivering beneficial agent. As such, Brodbeck will read on this limitation if it is reasonable to conclude that the products disclosed and suggested therein are capable of delivering drug over a time frame less than 7 days. Brodbeck's product has all of the same compositional elements and structural features as instantly claimed product, or for those features it is lacking Brodbeck suggests the features. As such, there is a reasonable basis to conclude that Brodbeck's product would be capable of delivering beneficial agent over less than seven days. Brodbeck thus meets this limitation of the claims as well.

It is noted that the instant invention attempts to solve the problem of burst release in prior art depot compositions. The instant disclosure recognizes that this problem is caused by such implants rapid imbibing of water. The solution in this Application is to use a gel implant that has a solvent that is poorly soluble in water, so that this rapid imbibing of water will be eliminated, and the burst effect will also be eliminated. Brodbeck recognizes the same problem in prior art depots as does the instant application. Col's 3-4. Brodbeck solves this problem in the same way, namely, by using a gel implant with a solvent that is poorly soluble in water. Col. 5. Because it appears that the prior art has already offered the same solution as this Application, it is

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not clear what contribution, if any, the instant Application attempts to make over the prior art.

Claims 7-26, 29-34, 36, 38-39, 44-56, 59-60, 105-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,130,200 to Brodbeck in view of WO 02/38185.

The teachings of Brodbeck were discussed above.

What is lacking are the solvents of instant claims, such as the mixture of benzyl alcohol and benzyl benzoate.

The '185 reference has been discussed previously. The most relevant teachings of the '185 reference are an injectable implant device comprising a beneficial agent, a PLGA polymer, and a solvent, wherein solvents such as benzyl alcohol, benzyl benzoate, and combinations thereof, are useable. Claim 7.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the solvents of the 185 reference. Obviousness stems from the notion that it is obvious to substitute materials that are known to be used for the same purpose in the art. Here, the solvents of 185 are used for the same type of implant as those of Brodbeck. As such, the substitution would be obvious and the artisan would enjoy a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman
Art Unit 1618